

supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:

- (i) Refuses the food served.
- (ii) Cannot tolerate the food served.
- (iii) Does not eat adequately.

(3) The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.

(b) *Sanitary conditions.* The PACE organization must do the following:

(1) Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization.

(2) Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions.

(3) Dispose of garbage and refuse properly.

[64 FR 66279, Nove. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

#### § 460.80 Fiscal soundness.

(a) *Fiscally sound operation.* A PACE organization must have a fiscally sound operation, as demonstrated by the following:

(1) Total assets greater than total unsubordinated liabilities.

(2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency.

(b) *Insolvency plan.* The organization must have a documented plan in the event of insolvency, approved by CMS and the State administering agency, which provides for the following:

(1) Continuation of benefits for the duration of the period for which capitation payment has been made.

(2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.

(3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

(c) *Arrangements to cover expenses.* (1) A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:

(i) One month's total capitation revenue to cover expenses the month before insolvency.

(ii) One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operations.

(2) Arrangements to cover expenses may include, but are not limited to, the following:

(i) Insolvency insurance or reinsurance.

(ii) Hold harmless arrangement.

(iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

#### § 460.82 Marketing.

(a) *Information that a PACE organization must include in its marketing materials.* (1) A PACE organization must inform the public about its program and give prospective participants the following written information:

(i) An adequate description of the PACE organization's enrollment and disenrollment policies and requirements.

(ii) PACE enrollment procedures.

(iii) Description of benefits and services.

(iv) Premiums.

(v) Other information necessary for prospective participants to make an informed decision about enrollment.

(2) Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.

(b) *Approval of marketing information.*

(1) CMS must approve all marketing information before distribution by the PACE organization, including any revised or updated material.

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(2) CMS reviews initial marketing information as part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.

(3) Once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following:

(i) *Time period for approval.* CMS approves or disapproves marketing information within 45 days after CMS receives the information from the organization.

(ii) *Deemed approval.* Marketing information is deemed approved, and the organization can distribute it, if CMS and the State administering agency do not disapprove the marketing material within the 45-day review period.

(c) *Special language requirements.* A PACE organization must furnish printed marketing materials to prospective and current participants as specified below:

(1) In English and in any other principal languages of the community.

(2) In Braille, if necessary.

(d) *Information on restriction of services.* (1) Marketing materials must inform a potential participant that he or she must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PACE organization or from an entity authorized by the PACE organization.

(2) All marketing materials must state clearly that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

(e) *Prohibited marketing practices.* A PACE organization must ensure that its employees or its agents do not use prohibited marketing practices which includes the following:

(1) Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age.

(2) Activities that could mislead or confuse potential participants, or misrepresent the PACE organization, CMS, or the State administering agency.

(3) Gifts or payments to induce enrollment.

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(4) Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment.

(5) Unsolicited door-to-door marketing.

(f) *Marketing Plan.* A PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

### Subpart F—PACE Services

#### § 460.90 PACE benefits under Medicare and Medicaid.

If a Medicare beneficiary or Medicaid recipient chooses to enroll in a PACE program, the following conditions apply:

(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.

(b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.

#### § 460.92 Required services.

The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(a) All Medicare-covered items and services.

(b) All Medicaid-covered items and services, as specified in the State's approved Medicaid plan.

(c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

[71 FR 71335, Dec. 8, 2006]

#### § 460.94 Required services for Medicare participants.

(a) Except for Medicare requirements that are waived for the PACE program, as specified in paragraph (b) of this section, the PACE benefit package for Medicare participants must include the following services:

(1) The scope of hospital insurance benefits described in part 409 of this chapter.